

## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



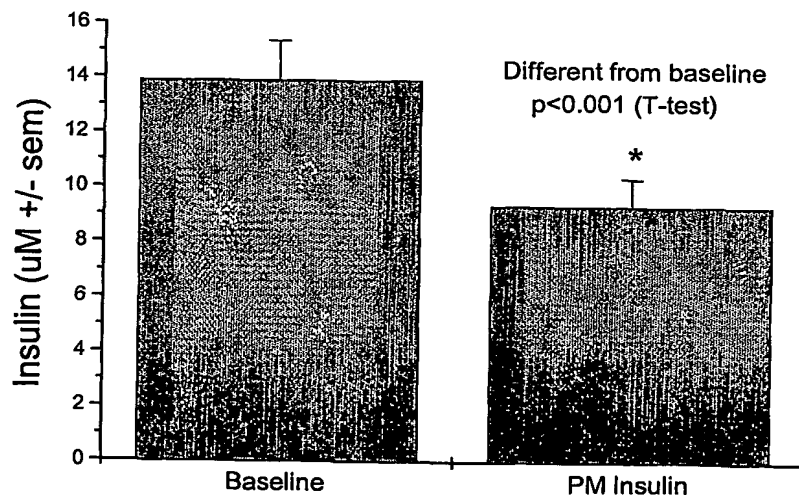
(43) International Publication Date  
29 July 2004 (29.07.2004)

PCT

(10) International Publication Number  
**WO 2004/062587 A2**

- (51) International Patent Classification<sup>7</sup>: **A61K**
- (21) International Application Number:  
PCT/US2004/000273
- (22) International Filing Date: 6 January 2004 (06.01.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/438,195 6 January 2003 (06.01.2003) US  
60/438,451 6 January 2003 (06.01.2003) US  
60/478,967 16 June 2003 (16.06.2003) US
- (71) Applicant (for all designated States except US): **EMI-SPHERE TECHNOLOGIES, INC.** [US/US]; 765 Old Saw Mill River Road, Tarrytown, NY 10591 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **GOLDBERG, Michael** [US/US]; 765 Old Saw Mill River Road, Tarrytown, NY 10591 (US). **ARBIT, Ehud** [US/US]; 765 Old Saw Mill River Road, Tarrytown, NY 10591 (US).
- (74) Agents: **DAVIDSON, Clifford, M.** et al.; Davidson, Davidson & Kappel, LLC, 14th Floor, 485 Seventh Avenue, New York, NY 10018 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— without international search report and to be republished upon receipt of that report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: NIGHT-TIME ORAL INSULIN THERAPY



(57) Abstract: A method for protection of a mammal that has impaired glucose tolerance or early stage diabetes mellitus from developing overt or insulin dependent diabetes comprises administering an orally effective dose of a pharmaceutical formulation comprising insulin at nighttime, e.g., at or shortly before bedtime.